IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

VISTA HEALTHPLAN, INC., *et al.*,	)	
Plaintiffs	)	No. 2:06-cv-1833
v.	)	
CEPHALON, INC., *et al.*,	)	
Defendants	)	

GENERIC DEFENDANTS' OPPOSITION TO END PAYOR PLAINTIFFS' MOTION FOR RECONSIDERATION AND FOR LEAVE TO FILE A SECOND AMENDED CONSOLIDATED COMPLAINT

Defendants Barr Laboratories, Inc., Mylan Inc. (formerly known as Mylan Laboratories, Inc.), Ranbaxy Laboratories, Ltd., Ranbaxy Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc. (collectively the "Generic Defendants") oppose the End Payor Plaintiffs' motion seeking leave to file a second amended complaint and for reconsideration of this Court's March 29, 2010 Order.

End Payor Plaintiffs' motion to file an amended complaint should be denied because the proposed amendments to the complaint are legally irrelevant given this Court's adoption of the "scope of the patent" test. Moreover, the End Payor Plaintiffs have had multiple bites at the proverbially apple. The defendants have invested ample time and resources responding to the various iterations of the End Payor Plaintiffs' efforts to insert life into their complaint. They simply cannot do so.

The motion for reconsideration should also be denied. Because End Payor Plaintiffs voluntarily withdrew their New York claim, and there has been no change in controlling law, there is no basis for this Court to reconsider its Order dismissing the New York claim.

I. The End Payor Plaintiffs Should Not Be Granted Leave to Amend Their Complaint Yet Again.

The Court should deny End Payor Plaintiffs leave to once again amend their complaint because the proposed amendments—which are fundamentally irrelevant to the Court's resolution of their antitrust claims—fail to state a cause of action and thus are futile.

The Third Circuit has repeatedly held that a court "may refuse to allow an amendment that fails to state a cause of action." *E.g.*, *Cureton v. Nat'l Coll. Athletic Ass'n*, 252 F.3d 267, 273 (3d Cir. 2001); *see also, e.g.*, *Oran v. Stafford*, 226 F.3d 275, 291 (3d Cir. 2000) (affirming the district court's denial of leave to amend because of futility of amendment). As that Court has explained, this is so because "it would be futile to amend the complaint to include a meritless claim." *Doug Grant, Inc. v. Greate Bay Casino Corp.*, 232 F.3d 173, 188-89 (3d Cir. 2000) (upholding the district court's denial of leave to amend). That is precisely the case here: The End Payor Plaintiffs' proposed amendments add no legally relevant allegations to support their antitrust claims, and thus the Court should deny leave to file their latest round of proposed amendments.

This Court held in its March 29, 2010 Memorandum Opinion that Plaintiffs' antitrust claims hinge on the question whether the Provigil® Settlements exceeded

the scope of the RE '516 Patent. *See* Mem. Op. 20. So now, End Payor Plaintiffs seek leave to amend their complaint to add two new paragraphs alleging that the Provigil® Settlements exceed the scope of the patent and violate the antitrust laws because "the patent itself was invalid, unenforceable and/or non-infringed." EPP Proposed Am. Compl. ¶ 9; *see also id.* ¶ 147.

But Plaintiffs cannot establish that the Provigil® Settlements exceeded the scope of the patent by alleging that the patent is invalid or not infringed by the Generic Defendants' versions of Provigil®. Every federal court that has adopted the scope of the patent test has held that the validity, enforceability, or non-infringement of the patent at issue is legally irrelevant to the antitrust analysis. *See, e.g., In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 530 (E.D.N.Y. 2005) ("[I]t is inappropriate for an antitrust court, in determining the reasonableness of a patent settlement agreement, to conduct an after-the-fact inquiry into the validity of the underlying patent."), *aff'd* 544 F.3d 1323 (Fed. Cir. 2008); *In re K-Dur Antitrust Litig.*, No. 01-1652, 2009 WL 508869, at *25 (D.N.J. Feb. 6, 2009) (Report and Recommendation of Special Master) ("it is inappropriate to conduct an *ex post* inquiry into infringement issues that were resolved by the parties' settlement"), *adopted by district court at* 2010 WL 1172995 (D.N.J. March 25, 2010). In addition, "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into," not years later. *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1306 (11th Cir. 2003). Any such after-the-fact analysis of the merits of the patent case is thus of "limited value

in assessing the behavior of the defendants at the relevant time: when they were entering into the Settlement Agreement." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 204 (2d Cir. 2006). Accordingly, an allegation that the patent was invalid, unenforceable, or not infringed fails to state a cause of action under the scope of the patent test.

Tamoxifen is particularly instructive on this point. In *Tamoxifen*, the Second Circuit affirmed an order of the district court dismissing an antitrust challenge to a Hatch-Waxman patent settlement, pursuant to Rule 12(b)(6). 466 F.3d at 216. In that case, the patent holder settled with the generic challenger *after the patent had been declared invalid by the district court* and while the case was on appeal. *Id.* at 205. The Second Circuit, applying the scope of the patent test, held that plaintiffs' claims failed as a matter of law—*even though the district court had found the patent invalid*. *Id.* at 218 ("[B]ecause [the settlement] did not exceed the scope of the tamoxifen patent, it was not an *unlawful* anticompetitive agreement." (emphasis added)). Similarly, the Eleventh Circuit has explained that "exposing settling parties to antitrust liability for exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid would undermine the patent incentives." *Valley Drug*, 344 F.3d at 1308.

The *only* question relevant to an antitrust court about the *underlying* patent litigation is whether it was "sham" (*i.e.*, whether a typical litigant raising the same claims would have had any reasonable belief that the claim would have been successful). (The End Payor Plaintiffs' proposed amendments do not include a

"sham" allegation.) The test thus is not whether the litigant *would have* won; the test is whether the litigant had a reasonable belief that it *might* have won. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). Courts make this *legal* determination (as to whether there was a good faith basis for a litigant's position) based on a review of the record, not an actual attempt to adjudicate the *outcome* of the prior litigation. *See, e.g., Organon, Inc. v. Mylan Pharmaceuticals, Inc.*, 293 F. Supp. 2d 453, 461-62 (D.N.J. 2003); *Pennpac International v. Rotonics Mfg. Co.*, No. 99-2890, 2001 WL 569264, at *6-7 (E.D. Pa. May 25, 2001); *see also K-Dur*, 2009 WL 508869, at *28 ("[T]he question of whether the suit was objectively baseless is a matter of law."). The test is "whether the suit was so objectively baseless that no reasonable litigant could realistically expect success on the merits." *K-Dur*, 2009 WL 508869, at *29 (quotations omitted). None of End Payor Plaintiffs' allegations of invalidity, unenforceability, or non-infringement satisfy this standard.

As the above "scope of the patent" and "sham" holdings make clear, the question of the RE '516 Patent's validity, or whether the Generic Defendants' products infringed that patent, are fundamentally irrelevant to the Court's present inquiry as to whether plaintiffs can succeed on their claims under the "scope of the patent" test. Far from seeking to "conform its claims to what the Court has already approved in its March 29 Order," EPP Mot. 7, the End Payor Plaintiffs' latest effort to amend their complaint evinces a fundamental misunderstanding of the law

relevant to their antitrust claims.[1] The proposed additional allegations are legally irrelevant and leave to amend should be denied.

Moreover, the motion for leave to file should be denied because End Payor Plaintiffs had ample opportunity to include such allegations prior to the Court's decision on the motions to dismiss. End Payor Plaintiffs have already amended their complaint once (after seeing all of the defendants' motion to dismiss arguments), and as detailed above, the proposed amended complaint adds no legally-cognizable allegation. This is precisely the type of "undue delay" that the Third Circuit has repeatedly held sufficient to deny leave to amend, even absent prejudice to the defendants. *See, e.g.*, *Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (upholding denial of leave to amend complaint on grounds of undue delay and futility even without prejudice to the defendants). There is nothing "new" in End Payor Plaintiffs' allegations; rather, it is an admitted (yet misguided) attempt to plead around this Court's holding on the motions to dismiss. There is simply no reason End Payor Plaintiffs could not have raised these same allegations when it amended its complaint months ago.

The Court should deny leave to file the proposed amendments.

[1] Other than typographical and spelling corrections, the only other amendments proposed by the End Payor Plaintiffs are attempts to characterize the Provigil® Settlements. The Generic Defendants disagree with these characterizations, which are also legally irrelevant. *See* Generic Defs.' MTD the Am. Compls. of the Direct Purchaser Pls. & End Payor Pls., at 6.

II. The Motion for Reconsideration Should Be Denied.

The End Payor Plaintiffs' motion for reconsideration should also be denied. This motion is based on the false premise that there was an intervening change in the law. *See* EPP Mot. 4. End Payor Plaintiffs argue that this Court should reconsider its Order dismissing their antitrust claim under New York law because "the state of the law changed just two days after the Court issued its decision [on the motion to dismiss]." EPP Mot. 4. End Payor Plaintiffs claim that they withdrew their New York claims "only in the face of law cited by Defendants in their motion to dismiss"—the New York Court of Appeals' decision in *Sperry v. Crompton Corp.*, 831 N.Y.S.2d 760, 765-66 (2007)—which End Payor Plaintiffs argue "has now been reversed by the Supreme Court." EPP Mot. 5 (citing *Shady Grove Orthopedic Associates, P.A. v. Allstate Ins. Co.*, No. 08-1008, --- S.Ct. ----, 2010 WL 1222272 (Mar. 31, 2010)).

This is incorrect for at least two reasons. As an initial matter, the Supreme Court's decision in *Shady Grove* did *not* overrule or reverse the New York Court of Appeals' decision in *Sperry*. The issue in *Sperry* was whether New York Civ. L. § 901(b), which prohibits class actions in suits seeking penalties or statutory minimum damages, prohibits a plaintiff from maintaining a Donnelly Act claim as a class action in New York state court. *See Sperry*, 831 N.Y.S.2d at 765-66. It goes without saying that the U.S. Supreme Court cannot reverse the New York Court of Appeals on an issue of New York law. *See Erie R. Co. v. Tompkins*, 304 U.S. 64, 79 (1938) (holding that a federal court sitting in diversity looks to the decisions of the highest state appellate court on matters of state law). What the Supreme Court

held in *Shady Grove* is that, in actions pending in federal court, it is Federal Rule 23, and not New York § 901(b), that determines whether an action can be maintained as a class action. *Shady Grove*, 2010 WL 1222272, at *8. Nor did the holding in *Shady Grove* change the controlling law with respect to the End Payor Plaintiffs' claim. At the time of *Shady Grove*, only one federal court—the U.S. Court of Appeals for the Second Circuit—had ruled on the issue presented in that case. *Id.* at *3. Neither the Second Circuit's ruling nor the opinion in *Sperry* was binding with respect to End Payor Plaintiffs' claim in this Court, meaning there was no intervening change in the law that would warrant reconsideration.

The End Payor Plaintiffs thus did not, as they imply, withdraw their claim in the face of controlling authority that was later reversed. Instead, End Payor Plaintiffs made a strategic decision not to pursue the New York law claim *despite* the fact that the *Shady Grove* case was pending and the arguments made by the litigants in *Shady Grove* were well known. The End Payor Plaintiffs certainly could have raised the same argument advanced by the plaintiffs in *Shady Grove*—that Federal Rule 23, and not New York § 901(b), applied to purported class actions in federal court. If End Payor Plaintiffs had done this, and this Court had denied their argument, a motion for reconsideration might be well-founded. But End Payor Plaintiffs decided not to raise this argument, and instead withdrew their claims. End Payor Plaintiffs cannot now go back in time and reverse their strategic decision now that this Court has ruled. As this Court has long held, "[a] motion for reconsideration may not be used as a vehicle to assert new arguments that could

have been but were not previously presented to the court." *Barrett v. West Chester Univ. of Pennsylvania of State Sys. of Higher Educ.*, 636 F. Supp. 2d 439, 443 (E.D.Pa. 2009); *see also Hower v. Wal-Mart Stores, Inc.*, No. 08-1736, 2009 WL 2047892, at *2 (E.D. Pa. July 10, 2009) (same); *Vaidya v. Xerox Corp.*, No. 97-547, 1997 WL 732464, at *4 (E.D. Pa. Nov. 25, 1997) (similar).

The End Payor Plaintiffs made a strategic decision not to argue that Rule 23, and not New York § 901(b), applied to their federal court action. They were not required to do so, and there was no controlling law that doomed their claim when they elected to do so. This Court accepted their strategic decision to withdraw the claim and granted the motion to dismiss. End Payor Plaintiffs should not be allowed to reverse this decision after the parties have spent time briefing and arguing the motions to dismiss, and the Court has spent time and resources adjudicating them. *See Hower*, 2009 WL 2047892, at *2 ("Due to the strong interest in the finality of judgments, courts should grant motions for reconsideration sparingly."). The motion for reconsideration should be denied.

CONCLUSION

For the foregoing reasons, the Court should deny the End Payor Plaintiffs' motion for reconsideration and for leave to file a second amended complaint.

April 29, 2010

Respectfully submitted,

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[PROPOSED] ORDER DENYING THE END PAYOR PLAINTIFFS' MOTION FOR RECONSIDERATION AND FOR LEAVE TO FILE A SECOND AMENDED COMPLAINT

Having considered the End Payor Plaintiffs' Motion for Reconsideration and for Leave to File a Second Amended Complaint, and the oppositions thereto, it is hereby ORDERED that the End Payor Plaintiffs' Motion is DENIED.

Dated: _____

_____
Hon. Mitchell S. Goldberg
United States District Judge

CERTIFICATE OF SERVICE

The undersigned certifies that on the 29th day of April 2010 he caused to be filed electronically the foregoing GENERIC DEFENDANTS' OPPOSITION TO END PAYOR PLAINTIFFS' MOTION FOR RECONSIDERATION AND FOR LEAVE TO FILE A SECOND AMENDED CONSOLIDATED COMPLAINT using the CM/ECF system, which will send e-mail notification of the filing to all counsel of record.

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